510(k) Summary of Safety and Effectiveness

Date Summary Prepared: September 18, 2012

SEP 21 2012

Applicant/Sponsor: Harvest Technologies Corporation
40 Grissom Road, Suite 100
Plymouth, MA 02360
Phone Number: 508-732-7541
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Contact Person: Susan Finneran - Director Regulatory Affairs

Device Trade Name: Harvest AdiPrep™ Adipose Transfer System
Common name: Fat Concentration System
Classification Name: Lipoplasty System, Class II
(21 CFR 878.5040, Suction Lipoplasty System,
Product Code MUU)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed: K081848, Viafill System, Lipose Corporation and, K100114, Vortech Adipose Transfer System, Biomet Biologics, Inc.

Device Description: The Harvest AdiPrep Adipose Transfer System consists of a disposable process pack to be utilized with the SmartPReP2 centrifuge. The process pack is a sterile (EtO) single use disposable pack used for the aspiration, harvesting, and transferring of autologous adipose tissue. It is intended for the concentration of aspirated adipose tissue for subsequent transfer during the same procedure.

Indications for Use: The AdiPrep™ Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep™ Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

- Neurosurgery
- Gastrointestinal Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General surgery
- Orthopedic Surgery

- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
- Arthroscopic Surgery

Substantial Equivalence: The device system has been cleared by the FDA by the 510(k) Premarket Notification process. This submission describes this new adipose concentration system as compared to the predicate devices.

Technological Characteristics:

Based on the intended use, design, materials, and technological characteristics presented in this premarket notification as summarized in Table 1 below, the Harvest AdiPrep Adipose Transfer System has been shown to be substantially equivalent to the currently marketed predicate devices. Biocompatibility testing was conducted as per ISO 10993 to demonstrate that the materials used in the manufacture of the the AdiPrep Adipose Transfer System are suitable for the intended use.

Clinical Testing: Clinical testing was performed to determine substantial equivalence to the predicate device. The testing included verification that the output of the AdiPrep Adipose Transfer System is substantially equivalent to the predicate Viafill System (Lipose Corp.) and the Vortech Adipose Transfer System (Biomet Biologics). The results indicated the devices were functional within their intended use. A summary of the results appears in Table 1 below.

Table 1: SUBSTANTIAL EQUIVALENCE COMPARISON CHART

FEATURES	DEVICES		
	AdiPrep Adipose Transfer System (This submission)	**Lipose Fat Transfer System, K081848, (Predicate device)**	**Biomet Vortech™ Adipose Transfer System (VATS), K100114, (Predicate device)**
Indications for Use (IFU)	The AdiPrep™ Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep™ Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, Arthroscopic Surgery	The Lipose Fat Transfer System is intended to be used in the aspiration, harvesting, and reinjecting of autologous fat.	The Vortech™ Adipose Transfer System (VATS) is used in medical procedures involving the harvesting and transferring of autologous fat tissue. The VATS System is used for concentrating fat harvested with a legally marketed lipoplasty system. The VATS System is intended for use in the following surgical specialties when the concentration of adipose tissue is desired. • Neurosurgery • Gastrointestinal and Affiliated Organ Surgery • Urological Surgery • Plastic and Reconstructive Surgery • General Surgery • Orthopedic Surgery • Gynecological Surgery • Thoracic Surgery • Laparoscopic Surgery

FEATURES	• DEVICES		
	AdiPrep Adipose Transfer System (This submission)	**Lipose Fat Transfer System, K081848, (Predicate device)**	**Biomet Vortech™ Adipose Transfer System (VATS), K100114, (Predicate device)**
Processing Pack: -Materials	Components-syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle. Cannula & syringes composed of medical grade plastics.	Components-syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle.	The materials used in the Fat Concentrator, syringes, and accessories consist of medical grade polymers, elastomers, and stainless steel suitable for use in medical devices. All components are packaged, labeled and sterilized as indicated by the manufacturer labeling.
-Fill volumes (mL)	Volume = 5 mL to 25 mL	Volume = 5 mL to 20 mL	Volume = 180 mL
-Sterilization Method	Ethylene-Oxide Gas (EtO)	Gamma Radiation	Gamma Radiation
Autologous Adipose Product* Nucleated Cell Count ($x10^5$/ml of Product)	Mean 1.823	Mean 1.848	Actual results are not available, however, in K100114, Biomet reported that testing "by direct comparison included verification that the output of the Vortech™ Adipose Transfer System (VATS) is substantially equivalent to the Viafill™ System (Lipose Corp.), the predicate device. Test results for both percent volume reduction and percent cell viability show that the VATS System is substantially equivalent to the Viafill System."
-Nucleated Cell Viability (%)	Mean 83.5	Mean 82.4	
Processing Capabilities			
Volume	Volume = 5 mL to 25 mL	Volume = 5 mL to 20 mL	Volume = 180 mL
Low-*g-force*	Centrifuge to spin for approximately 4 minutes at 1250 g-force.	Centrifuge to spin for 2 minutes at 50 g-force.	4 ½ minute centrifugation process , g-force unknown.
Laboratory Centrifuge	SmartPReP2 Centrifuge is a general purpose laboratory centrifuge for clinical use.	Viafill™ System centrifuge is a general purpose laboratory centrifuge.	The VATS reusable portable tabletop base unit is similar to a general purpose laboratory centrifuge.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Harvest Technologies Corporation
% Mr. Gabriel J. Muraca, Jr.
Regulatory Affairs Manager
40 Grissom Road, Suite 100
Plymouth, Massachusetts 02360

SEP 21 2012

Re: K121005
Trade/Device Name: AdiPrep™ Adipose Transfer System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: August 29, 2012
Received: August 30, 2012

Dear Mr. Muraca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121005

Device Name: AdiPrep™ Adipose Transfer System

Indications for Use:

The AdiPrep™ Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The AdiPrep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep™ Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

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- Laparoscopic Surgery
- Arthroscopic Surgery

Prescription Use _____x__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121005